



California Drug Recall Information



Recall Name

**Alexion Recalls Soliris® (eculizumab)
Concentrated Solution for Intravenous Infusion
Due to Visible Particulate Matter**

Recall Date	Product Description	Recalling Firm	Recall Reason
06/02/14	Soliris® (eculizumab) 300mg/30mL Concentrated Solution for Intravenous Infusion NDC 25682-001-01	Alexion Pharmaceuticals, Inc. Cheshire, CT	<i>Due to the presence of visible proteinaceous particles detected in a single lot (10007A) during periodic stability testing.</i> <i>Alexion is including additional lots in the recall, which were produced with the same process component believed to cause the particulate during vial filling.</i>
Recall Class	Product Identification	Distribution	Affected Dates
N/A	Suspect Lots: 10007A 10005A 10002-1 10005A 00006-1 10006A 10003A 10008A 10004A Product Labels	CA , nationwide	Affected lot was last shipped on October 30, 2013.

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/Safety/Recalls/ucm399527.htm>